PREMARKET NOTIFICATION [510(K)] SUMMARY

June, 2007

K071732

Trade Name:	StemCor Systems, Inc. MarrowMiner
Common Name:	Biopsy instrument
Classification Name:	Instrument, biopsy (per 21 CFR section 876.1075)
Manufacturer's Name:	StemCor Systems, Inc. 801 Hermosa Way Menlo Park, CA 94025
	SEP 2 4 2007
Corresponding Official:	Sharon Rockwell Consultant 5582 Chalon Road Yorba Linda, CA 92886 Phone: (714) 695-9269 Fax: (714) 779-1239
Predicate Device(s):	Biomedical Eng, Inc. BoneHog/Excaliber, K961902, K964073, K971783. Medical Device Technologies, Inc. InterV SnareLok Bone Marrow Biopsy Needle, K043523. Vidacare Bone Marrow Aspiration Set, K062833
Device Description:	The MarrowMiner is a device intended for harvesting bone marrow. The StemCor MarrowMiner bone marrow collection system is comprised of four components; a MarrowMiner battery powered handle, an aspiration chamber, a flexible aspiration shaft, and an access guide. The tip of the flexible aspiration shaft rotates and aspirates bone marrow. The device has been shown in animal studies to obtain adequate bone marrow samples without compromising the iliac crest integrity.
Intended Use:	For harvesting bone marrow.
Technological Characteristics:	Aspiration module and flexible shaft allow the marrow to be collected under controlled vacuum through a single puncture until the desired volume is collected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 2007

Stemcor Systems, Inc.
% Rockwell & Associates
Ms. Sharon Rockwell
Consultant, Regulatory Affairs
5582 Chalon Road
Yorba Linda, California 92886

Re: K071732
Trade/Device Name: StemCor Systems, Inc. MarrowMiner
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachments
Regulatory Class: I
Product Code: GDM, GAA
Dated: August 30, 2007
Received: August 31, 2007

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071732

Device Name: StemCor Systems, Inc. MarrowMiner

Indications for Use:

The MarrowMiner is intended for harvesting bone marrow.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071732